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105TH CONGRESS
1ST SESSION

H. R. 1411

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 23, 1997

Mr. BURR of North Carolina (for himself, Mr. GREENWOOD, Mr. BARTON of Texas, Mr. KLUG, Mr. COBURN, and Mr. DEAL of Georgia) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE, REFERENCE, AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Drug and Biological Products Modernization Act of 1997".

(b) REFERENCE.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(c) TABLE OF CONTENTS.—The table of contents is as follows:

SEC. 2. FDA MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as sub-

sections (c) and (d), respectively, and by adding after subsection (a) the following:

''(b) MISSION.—The Food and Drug Administration shall protect the public health by ensuring that—

''(1) foods are safe, wholesome, and sanitary;

''(2) human and veterinary drugs are safe and effective;

''(3) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(4) cosmetics are safe; and

''(5) public health and safety are protected from electronic product radiation.

The Food and Drug Administration shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.''

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is amended by adding at the end the following:

''(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for

the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

''(1) review the performance of the Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

''(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements and statutory deadlines for the approval of products or for other purposes contained in this Act;

''(3) describe the staffing and resources of the Food and Drug Administration and list those persons and organizations accredited to conduct investigations under sections 505(i) and 520(g), to review drugs under section 505, to make initial classification of devices under section 513, and to perform good manufacturing practice reviews under sections and 520(f); and

''(4) describe the goals, activities, and accomplishments of the Food and Drug Administration in bilateral and multinational meetings that addressed methods and approaches to reduce the burden of

regulation, harmonize regulation, and to seek appropriate reciprocal arrangements, list each such meeting, and list pending issues specifying those that are not consistent with or are contrary to the provisions of this Act.

''(f) GAO ANNUAL REPORT.—The Comptroller General of the United States shall each January submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report which compares—

''(1) the performance of the Food and Drug Administration in approving innovative drug, device, human tissue, and food products with that of agencies performing similar functions in countries listed in section 802(b); and

''(2) the resources used by agencies in such countries to approve such products.

In developing a methodology for the report, the Comptroller General shall consult with representatives of the Secretary, the regulated industry, academic experts in the field, and experts knowledgeable about information in such other countries so that the approach accurately presents the information in a fair and balanced manner.

SEC. 3. STREAMLINING CLINICAL RESEARCH ON DRUGS AND BIOLOGICAL PRODUCTS.

Section 505(i) (21 U.S.C. 355(i)) is amended by adding ''(1)'' prior to the first sentence, by redesignating paragraphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively, and by adding the following new paragraphs at the end thereof:

''(2) A clinical investigation of a new drug may begin 30 days after the Secretary has received from the sponsor of the investigation a submission containing information about the drug and the clinical investigation as follows: The submission shall contain—

''(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

''(B) adequate information on the chemistry of the drug, manufacturing of the drug, controls available for the drug, and primary data tabulations for the drug from animal or human studies, except that for phase I clinical investigations detailed information for drugs and well-characterized therapeutic, biotechnology derived drugs shall not be required unless the director of the office responsible for the review of the drug makes a request within 30 days

after the submission regarding such detailed information in writing and specifies the reasons for the request.

''(3)(A) At any time, the Secretary may issue to the sponsor of an investigation a clinical hold confirmed in writing prohibiting the sponsor from conducting the investigation and specifying the basis for the clinical hold. The Secretary may issue a clinical hold upon a demonstration, based on specific information available to the Secretary, that the drug to be investigated represents an unreasonable risk to the safety of the persons who are the subject of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, and the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved.

''(B) Any response from the sponsor of an investigation to the Secretary requesting that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such response or the clinical hold shall be deemed to be withdrawn.

''(4)(A) As an alternative to the procedure established in paragraph (2), a Phase I or Phase II non-commercial clinical investigation may begin after an accredited

institution, accredited by the Secretary under subparagraph (B) to conduct the specific type of investigation which is the subject of such research, has approved the investigation and the sponsor of the investigation has submitted to the Secretary a notification setting forth the name and address of the sponsor, the identity of the drug, and the uses of the drug that the sponsor intends to investigate. Data and information developed through such an investigation may be submitted in support of an application for approval of a new drug and shall be considered by the Secretary to the same extent as data and information developed through an investigation under paragraph (2). Paragraph (3) shall apply to such an investigation.

''(B) The Secretary shall establish and provide an opportunity for public comment on the requirements and qualifications that an accredited institution, which may include medical colleges and other organizations, shall meet to be eligible to approve an investigation for purposes of this paragraph.

''(5) The Food and Drug Administration shall have exclusive regulatory jurisdiction in the Department of Health and Human Services over the use of a new drug in any clinical investigation.''.

SEC. 4. THE CONTENT AND REVIEW OF A NEW DRUG APPLICATION.

(a) SECTION 505(b).—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(4)(A) Within 1 year after the date of the enactment of the Drug and Biological Products Modernization Act of 1997, the Secretary, in order to minimize the burden of unnecessary information submissions and to better harmonize international regulatory requirements, shall, after consultation with patient advocacy groups and the regulated industry, publish in the Federal Register criteria for the type and amount of information relating to effectiveness to be included in an application for the approval of a new drug or a new use of an approved drug. In developing the criteria, the Secretary shall consider any recommendations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

''(B) The Secretary shall establish standards for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and a knowledge of regulatory and scientific standards which shall apply equally to outside reviewers and to employees of the Secretary who review such applications.

''(C) Food and Drug Administration employees shall meet with a sponsor of an investigation or an applicant under an application for a new drug or a new use of an approved drug submitted under paragraph (1) within 30 days of any reasonable request for a meeting by the sponsor or applicant for the purpose of reaching agreement on the design and size of clinical trials. Minutes of any such meeting shall be exchanged. Advice provided to a sponsor or applicant at its request by a Food and Drug Administration employee, which is reduced to writing and made part of the administrative record by the sponsor or applicant or by the Food and Drug Administration, regarding appropriate testing of a new drug shall not be changed after such testing begins, except with the written agreement of the sponsor or applicant or by a decision in writing, after an informal hearing, by the director of the office in which the drug is reviewed where such change is needed because there is a demonstrated need to protect the public health or a valid safety consideration.

''(D) The written decisions of the office responsible for the review of a drug on all aspects of scientific and medical matters relating to a new drug shall be binding upon, and may not directly or indirectly be changed by, the field personnel of the offices of compliance of the office responsible for the review unless in consultation with the

reviewing office, such field personnel demonstrate why such decision should be modified.

''(E) No action by the office responsible for the review of a drug on any matter relating to a new drug for which an application has been submitted under paragraph (1) may at any time, or under any circumstance other than a demonstrable extraordinary circumstance, be delayed because of the unavailability of information from or action by field personnel unless the field personnel demonstrate to the office that such a delay is necessary to assure the marketing of a safe and effective drug.''.

(b) SECTION 505(j).—

(1) AMENDMENT.—Section 505(j) (21 U.S.C 355(j) is amended by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively, and by adding after paragraph (2) the following:

''(3)(A) The Secretary shall establish standards for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and a knowledge of regulatory and scientific standards which shall apply equally to outside reviewers and to employees of the Secretary who review such applications.

''(B) Food and Drug Administration employees shall meet with a sponsor of an investigation or an applicant under an application submitted under paragraph (1) within 30 days of any reasonable request for a meeting by the sponsor or applicant for the purpose of reaching agreement on the design and size of bioavailability or bioequivalence studies. Minutes of any such meeting shall be exchanged. Advice provided to a sponsor or applicant at its request by a Food and Drug Administration employee, which is reduced to writing and made part of the administrative record by the sponsor or applicant or by the Food and Drug Administration, regarding bioavailability or bioequivalence studies shall not be changed after such testing begins, except with the written agreement of the sponsor or applicant or by a decision in writing, after an informal hearing, by the director of the office in which the drug is reviewed where such change is needed because there is a demonstrated need to protect the public health or a valid safety consideration.

''(C) The written decisions of the office responsible for the review of a drug on all aspects of scientific and medical matters relating to a new drug shall be binding upon the field personnel of the offices of compliance of the office responsible for the review unless in consultation

with the reviewing office, such field personnel demonstrate why such decision should be modified.

''(D) No action by the office responsible for the review of a drug on any matter relating to a new drug for which an application has been submitted under paragraph (1) may at any time, or under any circumstance other than a demonstrable extraordinary circumstance, be delayed because of the unavailability of information from or action by field personnel unless the field personnel demonstrate to the office that such a delay is necessary to assure the marketing of a safe and effective drug.''.

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j) is amended—

(A) in paragraph (2)(A)(i), by striking ''(6)'' and inserting ''(7)'';

(B) in paragraph (3), by striking ''(4)'' and inserting ''(5)'';

(C) in paragraph (3)(I), by striking ''(5)'' and inserting ''(6)''; and

(D) in paragraph (6)(C), by striking ''(5)'' each place it occurs and inserting ''(6)''.

SEC. 5. EFFECTIVENESS DETERMINATION.

Section 505(d) (21 U.S.C. 355(d)) is amended—

(1) by adding after the last sentence the following: ''Substantial evidence may, where there is a

high level of confidence in the scientific validity of the results of an adequate and well-controlled investigation, consist of data from an adequate and well-controlled investigation and adequate supportive scientific evidence (obtained before or after such investigation).'';

(2) by adding at the end the following: ''For purposes of the preceding sentence, a well-controlled investigation shall only include methods of control that are appropriate to the disease or condition for which a drug is intended as prescribed, recommended, or suggested in its labeling. The Secretary may waive the requirement to conduct any well-controlled investigation, as defined in the preceding sentence.''; and

(3) by inserting ''(1)'' after ''(d)'', by redesignating clauses (1) through (7) as clauses (A) through (G), by striking ''(1) through (6)'' and inserting ''(A) through (G)'', and by adding at the end the following:

''(2) For purposes of paragraph (1)—

''(A) the Secretary shall, for the purpose of making an evaluation of a new drug for a serious or life-threatening condition, consider whether the benefits of the drug outweigh the known and potential

risks of the drug and the need to answer remaining questions about risks and benefits of the drug, taking into consideration the severity of the diseases and the absence of no comparable or satisfactory alternative therapy; and

''(B) concurrent with the approval of a drug described in clause (i), the Secretary may seek agreement from the sponsor of such drug to conduct certain postmarketing studies to delineate additional information about such drug's risks, benefits, and optimal use.

''(3) For the purpose of making an evaluation of an application submitted for a new use of a previously approved new drug, the Secretary shall consider whether the new use is supported by adequate valid scientific information from clinical investigation reports in peer reviewed medical and scientific journals, patient registries or compendia, and other sources recognized by the Secretary. In carrying out the preceding sentence, the Secretary may, as appropriate, consult with medical speciality societies.

''(4) For purposes of paragraph (1), the determination of effectiveness shall not include any potential use not explicitly included in the labeling, except for public health reasons.

SEC. 6. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

''(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or biological product or the approval for marketing of a drug or biological product under section 505, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this subsection, or both. Scientific advisory panels shall consider scientific issues and shall not include considerations of cost, economic aspects, comparative effectiveness, or legal matters.

''(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

''(3) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the drugs and biological products to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in, the development, manufacture, or utilization of, such drugs or biological products. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately

diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the drug and biological product manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

''(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest upon public disclosure of such conflict of interest if such waiver contributes to the ability of a panel to contribute to the public health, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

''(5) The Secretary shall provide education and training to each new panel member before such member participates in a panel's activities. Such education and training shall include a familiarization with certain requirements under this Act and any related regulation of the Secretary and the administrative process and procedures related to panel meetings.

''(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime. While so serving away from their homes or regular places of business, each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(7) The Secretary shall take whatever action is necessary to ensure that regular meetings are held by scientific advisory panels, at appropriate intervals and for a sufficient length of time, so that any matter to be reviewed by any such panel shall be presented to the panel not more

than 60 days after the matter is ready for review by the panel. Meetings of the panel may be held using electronic communication to convene the meeting.

''(8)(A) Any person whose drug is the subject of a scientific advisory panel shall have the same rights and responsibilities as the Secretary regarding—

''(i) the submission of written information to a scientific advisory panel;

''(ii) the participation of the persons at meetings of the panel; and

''(iii) access to data and information submitted to a scientific advisory panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code).

''(B) In a case in which a scientific advisory panel reviews an application submitted under section 505 or section 351 of the Public Health Service Act (including a petition, notification, or other similar request), all related data and information that are not available for public disclosure under section 552 of title 5, United States Code, shall be exchanged between the applicant and the Food and Drug Administration at the time the data and information are submitted to such panel but shall not otherwise be publicly disclosed.

''(C) Any meetings of a scientific advisory panel shall provide adequate time for initial presentations and for response to any differing views and shall encourage free and open participation by all interested persons.

''(9) Within 30 days after the date a scientific advisory panel makes its conclusions and recommendations on any matter under review by the panel, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, shall make a final decision on the matter, and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

''(10) A scientific advisory panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act. Such a panel shall make an annual report of its activities to the Secretary.''.

SEC. 7. MARKETING APPROVAL.

(a) SECTION 505.—

(1) SUBSECTION (b).—Section 505(b) (21 U.S.C. 355(b)), as amended by section 4(a), is amended—

(A) in the first sentence of paragraph (1), by inserting immediately before the period the

following: ''or and the Secretary may request a review of all or part of such application by an accredited person authorized to review applications for marketing approval , upon concurrence of the sponsor, and the Secretary shall pay for such review with fees authorized by section 736''; and

(B) by adding after paragraph (4) the following:

''(5) The scope of review responsibilities of an accredited person authorized to conduct reviews of marketing approval applications shall include the review of all or part of an application as requested by the Secretary . The accredited person shall submit a report of its review, including the basis for any recommendation to the Secretary.

(2) SUBSECTION (j).—Section 505(j)(1) (21 U.S.C. 355(j)(1)) is amended by adding at the end the following: ''The Secretary may request a review of all or part of such an application by an accredited person authorized to review applications for marketing approval upon concurrence of the sponsor. The scope of review responsibilities of such an accredited person shall include the review of all or part of such an application as requested by the Secretary. The accredited person shall submit a report of its review,

including the basis for any recommendation to the Secretary.''.

(b) SECTION 735(7).—Section 735(7) is amended—

(1) by striking ''applications for'' and inserting ''applications'' and by inserting ''for'' after ''(A)'', ''(B)'', and ''(C)'';

(2) by striking ''and'' at the end of subparagraph (C),

(3) by striking the period at the end of subparagraph (D) and inserting '', and'', and

(4) by inserting the following after subparagraph (D):

''(E) by outside organizations and individuals.''.

SEC. 8. ACCREDITATION OF THIRD PARTIES.

(a) AMENDMENT.—Subchapter A of chapter VII is amended by adding at the end the following:

''SEC. 712. ACCREDITED PERSONS.

''(a) IN GENERAL.—The Secretary shall, within 180 days of the date of the enactment of this section, by regulation establish procedures for the accreditation of persons for the purposes of reviewing applications under section 505(b), or under section 351 of the Public Health Service Act, providing written reviews to the Secretary for the

Secretary's consideration, and making recommendations on whether or not such applications should be approved.

''(b) ACCREDITATION.—

''(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified non-government organizations.

''(2) ACCREDITATION.—

''(A) GENERAL RULE.—Within 180 days of the date of the enactment of this section, the Secretary shall establish and publish in the Federal Register requirements to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

''(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing when such person acts or fails

to act in a manner that is inconsistent with the purposes of this section or poses a threat to public health.

"(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

"(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

"(ii) take such additional measures as the Secretary determines to be appropriate.

"(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(e)(2) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

"(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

"(A) Such person shall be an independent organization which is not owned or controlled

by manufacturer, supplier or vendor of drugs and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

''(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

''(C) Such person shall not engage in the development, manufacture, promotion, or sale of drugs.

''(D) Such person shall be operated in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

''(i) certify that reported information accurately reflects data reviewed;

''(ii) limit work to that for which competence and capacity are available;

''(iii) treat information received, records, reports, and recommendations as proprietary information; and

''(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited.''.

(b) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 321) is amended by redesignating the second paragraph (u) as paragraph (v) and by adding after that paragraph the following:

''(w) in the case of a drug, device, or food—

''(A) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

''(B) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

''(C) the receipt by a person accredited under section 712 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.''.

SEC. 9. DISPUTE RESOLUTION.

Chapter V is amended by adding after section 505 the following:

''DISPUTE RESOLUTION

''SEC. 506. (a) In instances in which there is a scientific controversy between a regulated person and the Secretary regarding an obligation under this Act, and no

specific provision of this Act or regulations promulgated under this Act by the Secretary provides a right to review of the subject matter of the dispute, the Secretary, upon receipt of a request for review of the controversy from such a regulated person, shall refer the disputed issue—

''(1) to an existing (as of the date of the notification) scientific advisory panel having expertise related to the issue; or

''(2) to a special Government employee, as defined in section 202(a) of title 18, United States Code, or to a non-governmental person qualified to mediate or arbitrate the substance of such impasse who is acceptable to the Secretary and the applicant.

''(b) The applicant and representatives of the Secretary may consult with the panel, special Government employee, or non-governmental person on the matter referred. The panel, special Governmental employee, or non-governmental person shall submit to the Secretary and the applicant a report containing recommendations (including a statement of reasons for the recommendations) regarding the matter not later than 60 days after the date of the referral, or not later than 90 days after the date of the referral if the panel, special Governmental employee, or non-governmental person considers the additional 30 days to be necessary. Not later than 30 days after the

date of receiving the report, the Secretary shall, in writing, confirm or modify the recommendations received, providing reasons and reference to data before the panel, special Governmental employee, or non-governmental person for any modification. If the Secretary fails to act on such a recommendation within 30 days of its receipt, the recommendation of the panel, special Government employee, or non-governmental person shall be deemed to be the recommendation of the Secretary.

''(c) Whenever the Secretary fails to complete a premarket submission review under section 505 in a timely manner as prescribed by this Act and the regulations of the Secretary under this Act, the person who made the submission may request that the director of the office responsible for the review (or any successor entity) evaluate the failure to timely complete the review of the submission and issue an explanation for such failure and a new date for completion of the review. Such director shall complete such an evaluation within 14 days of the date a request is made for it.

''(d) The Federal Advisory Committee Act shall not apply to any scientific advisory panel acting under this section.''.

SEC. 10. GOOD MANUFACTURING PRACTICES.

(a) AMENDMENT.—Section 501(a) (21 U.S.C. 351(a)) is amended—

(1) by striking ''(a)(1)'' and inserting ''(a)(1)(A)'';

(2) by redesignating subclauses (A) and (B) in clauses (2) and (4) as subclauses (i) and (ii), respectively; and

(3) by redesignating clauses (2) through (6) as clauses (B) through (F), respectively;

(4) by adding at the end the following:

''(2) All chemistry, manufacturing, and controls which comply with an approved new drug application under section 505 or a license application under section 351 of the Public Health Service Act or with the opinion of an appropriate official in the component of the Food and Drug Administration responsible for the review of such chemistry, manufacturing, or controls and which is reduced to writing and made part of the administrative record shall be deemed to comply with current good manufacturing practice. The Secretary shall not take action to delay or prevent the manufacture or marketing of a drug under section 505 or section 351 of the Public Health Service Act for failure to conform to current good manufacturing practice unless there is reasonable probability of

harm to the public health or the Secretary determines in writing that the drug is—

''(A) not bioequivalent,

''(B) deviates from the specifications for the drug established in the approved new drug application from the specifications for the drug established by the manufacturer,

''(C) lacks adequate assurance that it will meet the represented sterility, or

''(D) has been rendered unsafe or ineffective.''.

(b) CONFORMING AMENDMENTS.—

(1) SECTION 303.—Section 303(g)(1)(B)(iii) (21 U.S.C. 333(g)(1)(B)(iii)) is amended by striking ''501(a)(2)(A)'' and inserting ''501(a)(1)(B)(i)''.

(2) SECTION 304.—Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended by striking ''501(a)(3)'' and inserting ''501(a)(1)(C)''.

(3) SECTION 512.—Section 512(a)(1) (21 U.S.C. 360c(a)(1)) is amended by striking ''501(a)(5)'' and inserting ''501(a)(1)(E)'', section 512(a)(2) (21 U.S.C. 360c(a)(2)) is amended by striking ''501(a)(6)'' and inserting ''501(a)(1)(F)'', and section 512(a)(3) (21 U.S.C. 360c(a)(3)) is amended by striking ''501(a)(5) or (6)'' and inserting ''501(a)(1)(E) or 501(a)(1)(F)''.

(4) SECTION 721.—Section 721(a) (21 U.S.C 379e(a)) is amended by striking ''501(a)(4)'' and inserting ''501(a)(1)(D)''.

(5) SECTION 802.—Sections 802(b)(1)(D) and 802(f)(1)(B) (21 U.S.C.382(b)(1)(D), 382(f)(1)(B)) are each amended by striking ''(a)(1), (a)(2)(A), (a)(3)'' and inserting ''(a)(1)(A), (a)(1)(B)(i), (a)(1)(C)'' .

SEC. 11. PILOT AND SMALL SCALE MANUFACTURE.

Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end thereof the following:

''(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval prior to scaling up to a larger facility, unless the Secretary demonstrates in writing and specifying in detail the reasons that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

SEC. 12. MANUFACTURING CHANGES.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following:

''SUBCHAPTER D—MANUFACTURING CHANGES

''SEC. 741. MANUFACTURING CHANGES.

''(a) IN GENERAL.—A change in the manufacture of a new drug or new animal drug may be made in accordance with this section.

''(b) CHANGES.—

''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from that established in the approved new drug application or new animal drug application or license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, or potency as they may relate to the safety or effectiveness of the drug.

''(2) REPORTS.—The applicant shall report such changes to the Secretary and may distribute drugs made after the changes as follows:

''(A) Minor modifications in facilities, minor changes in personnel, or other minor manufacturing changes, which are of a type determined by the Secretary to have minimal potential to adversely affect the identity, strength, quality, purity, or potency as they may relate to the safety or effectiveness of a drug, may be

made at any time and shall be reported annually with supporting data to the Secretary.

''(B) Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, or potency as they may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application. Major manufacturing changes are (i) changes in the qualitative or quantitative formulation or the specifications in the approved marketing application (unless exempted by the Secretary); (ii) changes which the Secretary determines by regulation or guidance require completion of an appropriate human study demonstrating equivalence to the drug manufactured before such changes; and (iii) other changes which the Secretary determines by regulation or guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.

"(C) All other manufacturing changes shall be reported to the Secretary in a supplemental application. Unless the Secretary notifies the applicant within 30 days that preapproval of the supplement is required, the applicant may distribute the drug before the application is approved. The Secretary will subsequently approve or disapprove the supplemental application. The Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of the supplemental application.".

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act with respect to manufacturing changes shall remain in effect for—

(1) a period of 12 months after the date of the enactment of this section, or

(2) until the Secretary's regulations implementing section 741 of such Act take effect,

whichever is sooner.

SEC. 13. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Sections 301(i)(1) and 301(j)(1) (21 U.S.C. 321(i)(1), 321(j)(1)) are each amended by striking ''506, 507,''.

(B) Section 501(k) (21 U.S.C. 351(k)) is repealed

(C) Section 502(k) (21 U.S.C. 352(k) is repealed.

(D) Sections 510(j)(1)(A) and 510(j)(1)(D) (21 U.S.C. 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking ''506, 507,''.

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting ''or'' at the end of subparagraph (B), by striking ''; or'' at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(F) Section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)) is amended by striking ''; and'' at the end of subparagraph (B) and inserting a period and by striking subparagraph (C).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357), as in effect on the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out ''or 507'', section 201(dd) (21 U.S.C. 321(dd)) is amended by striking ''507,'', and sections 201(ff)(2)(B) and 201(ff)(3) (21 U.S.C. 321(ff)(2)(B), 321(ff)(3)) are each amended by striking '', certified as an antibiotic under section 507,''.

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking ''507(d) or (g),''.

(C) Sections 301(i)(1) and 301(j) (21 U.S.C. 321(i)(1), 321(j)) are each amended by striking ''507,''.

(D) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking ''or 507''.

(E) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(F) Section 510(j)(1)(D) (21 U.S.C. 360(j)(1)(D)) is amended by striking ''507,''.

(G) Section 520(l) is amended by striking paragraph (4) and by striking ''or Antibiotic Drugs'' in the subsection heading.

(H) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(I) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking '', certification of such drug for such disease or condition under section 507,''.

(J) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking ''the submission of an application for certification of the drug under section 507,'', by inserting ''or'' at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(K) Section 526(b) (21 U.S.C. 360bb(b)) is amended by striking '', a certificate was issued for the drug under section 507,'' each time it appears and by striking '', approval of an application for certification under section 507,''.

(L) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking '', issue another certificate under section 507,''.

(M) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking '', if a certification is issued under section 507 for such a drug,'', and '', of the issuance of the certification under section 507,''.

(N) Section 704(a)(1) (21 U.S.C. 374) is amended by striking '', section 507 (d) or (g)''.

(O) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting ''or'' at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(P) Sections 5(b)(1)(A) and 5(b)(1)(B) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking ''or 507''.

(Q) Section 28(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking ''or 507''.

(R) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking ''507,'' each place it occurs.

(S) Section 1927(k)(2)(A)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)(A)(ii)(II)) is amended by striking ''or 507''.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end thereof the following:

''(h) EXPORTATION OF INSULIN AND ANTIBIOTICS.—Insulin and antibiotics may be exported without regard to the requirements in this section if the insulin and antibiotics meet the requirements of section 801(e)(1).''.

SEC. 14. NONPRESCRIPTION DRUGS.

Chapter V is amended by adding after section 510 (21 U.S.C. 360) the following:

''NONPRESCRIPTION DRUGS

''SEC. 511. All applications or petitions requesting that a drug be switched from prescription to nonprescription status and all other matters relating to nonprescription drugs shall be reviewed and acted upon solely by a single office in the Center for Drug Evaluation and Research or a successor entity, and that office shall report directly to the Director of the Center. A single scientific advisory panel may provide conclusions and recommendations regarding any such matter.''.

SEC. 15. INFORMATION SYSTEM.

Chapter IX is amended by adding at the end the following section:

"SEC. 906. INFORMATION SYSTEM.

"The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action. The system shall permit access by the applicant.".

SEC. 16. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII, as amended by section 12, is amended by adding at the end the following:

"SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

"SEC. 744. ENVIRONMENTAL IMPACT REVIEW

"No action by the Secretary proposed to be taken pursuant to this Act shall require the preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act of 1969 unless the Secretary finds that because of extraordinary circumstances the proposed action may have a significant effect, either directly or cumulatively, on the human environment.".

SEC. 17. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

(a) IN GENERAL.—Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 501(f), 501(h), 502(f)(1), 502(l), 502(o), 502(s), 502(t), 505, and sections 510 through 520 shall not apply to a drug or device that is compounded by a licensed pharmacist or licensed physician or other licensed practitioner authorized by State law to prescribe drugs or devices or both—

''(A) on the order of such a licensed physician or other licensed practitioner for an individual patient; or

''(B) in limited quantities, as determined by the principal State agency of jurisdiction which regulates the practice of pharmacy for that pharmacist, before receiving a valid order for an individual patient if the compounding of the drug or device is based on a history of receiving valid orders that have been generated solely within an established relationship between the pharmacist, and (i) the patient for whom the order will be given, or (ii) the physician or other licensed practitioner who will write such order.

Such sections shall not apply to a drug or device if such pharmacist or physician or other licensed practitioner does

no more than advertise or otherwise promote the compounding service and does not advertise or otherwise promote the compounding of a particular drug or device.

''(2) None of the provisions of this Act referred to in paragraph (1) shall apply to a bulk drug product or other drug, including an imported drug, that is intended for use by a licensed pharmacist or licensed physician or other licensed practitioner in compounding a drug or device on the order of a licensed physician or other licensed practitioner for an individual patient, except to the extent that the provision relates directly to the quality, purity, potency, or identity of such drug.''.

(b) WITHDRAWAL OF PROPOSED RULE AND GUIDELINE.—The proposed rule of the Secretary of Health and Human Services concerning exceptions to the current good manufacturing practices for makers of positron emission tomography drug products and the draft guideline on the manufacture of positron emission tomography drug products published in the Federal Register of February 27, 1995 (at 60 FR 10517-10520 and 60 FR 10593-10594) are null and void and the Secretary of Health and Human Services may not propose another proposed regulation or guideline respecting the same matters covered by the proposed regulation and guideline described in this subsection.

SEC. 18. HARMONIZATION.

Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

''(c)(1) The Secretary shall participate in meetings with other countries to discuss methods and approaches to reduce the burden of regulation, harmonize regulatory requirements, and seek appropriate reciprocal arrangements. The Secretary shall, within 180 days of the date of enactment of this subsection, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices.

''(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).''.

SEC. 19. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

''(h)(1) The Secretary shall not rely upon informal agency statements, including guidance documents, policy statements, points to consider documents, or any other statements that have not been promulgated in accordance with the rulemaking requirements of chapter V of title 5, United States Code, to require any action be taken to satisfy a requirement of this Act.

''(2) The Secretary shall publish notice in the Federal Register of the availability to the public of each type of statement identified in paragraph (1). Additionally, the Secretary shall undertake to make available all such statements by electronic or other similar means.''.

SEC. 20. EDUCATION AND RESEARCH; PRACTICE OF MEDICINE.

Chapter IX, as amended by section 15, is amended by adding at the end the following sections:

''SEC. 907. EDUCATION AND RESEARCH.

''(a) EDUCATION.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for scientific training, administrative process and procedure, and integrity issues.

''(b) RESEARCH.—The Secretary, acting through the Food and Drug Administration, may conduct or contract for scientific research only if it is directly related to the implementation of this Act.

''SEC. 908. PRACTICE OF MEDICINE.

''Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner, licensed by law to administer drugs and devices, to prescribe or administer any legally marketed drug or device

to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.''.

SEC. 21. DELEGATION OF AUTHORITY.

Section 903 (21 U.S.C. 393), as amended by section 2(b), is amended by adding at the end the following:

''(f) DELEGATION OF AUTHORITY.—The reference in sections 505(b)(4)(A), 505(b)(4)(C), 505(i)(2)(B), 505(n)(1), 701(n), and 505(a)(4)(E) to the authority of a specific official or position in the Food and Drug Administration to perform a particular function is an authority which shall be only exercised by such official or individual in such position and the authority to exercise such authority may not be delegated.''.

SEC. 22. PUBLICATION OF NOTICE OF DEVIATION.

Section 705 (21 U.S.C. 375) is amended by adding at the end the following:

''(c) The Secretary may make public or communicate to any person outside the Food and Drug Administration any information regarding a notice which informs a regulated person of a purported deviation from a requirement of this Act only after the Secretary has completed the investigation of such deviation, except as provided in subsection (b).''.

SEC. 23. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by striking ''SEC. 351. (a)'' and all that follows through ''barter, or exchange the same.'' and inserting the following:

''SEC. 351. (a)(1) Except as provided in paragraph (6), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with the proper name of the biological product contained therein, the name, address, and applicable license number of the manufacturer of the biological product, and the expiration date of the biological product.

''(2) The license required under paragraph (1)(A) shall, as determined by the Secretary, cover the biological product, any facility in which the biological product is manufactured, processed, packed, or held, or both the product and facility.

''(3)(A) The Secretary shall establish, by regulation, requirements for license applications for biological products.

''(B) Except as provided in subparagraph (D), a license application that covers a biological product shall be approved based upon a demonstration that—

''(i) the product that is the subject of the application is safe and effective in accordance with subsections (c) and (d) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or meets standards designed to ensure that the product is safe, pure, and where appropriate, potent; and

''(ii) the methods used in, and the facilities and control used for, the manufacture, processing, packing, and holding of such product meet standards designed to ensure that the product meets the requirements of clause (i).

''(C) A license application that covers a facility shall ensure that the product and the facility meet standards designed to ensure that the product meets applicable requirements of subparagraph (B).

''(D) A license application for blood or a blood component (including plasma) shall be approved based on a demonstration that the product meets standards designed to assure that such product is safe, pure, and where appropriate, potent, and that the facility in which the product is manufactured, processed, packed, or held meets

standards designed to ensure that such product is safe, pure, and where appropriate, potent.

''(4)(A) Requirements prescribed under paragraph (3) shall include a requirement for preapproval inspection under subsection (c).

''(B) A license shall be approved only on condition that the licensee agrees to permit inspection of the facility of the licensee in accordance with subsection (c).

''(5)(A) Except as provided in subparagraph (C), an approved license for a biological product may be revoked if the Secretary determines, on the record after providing an opportunity for a hearing in accordance with section 554 of title 5, United States Code, that the requirements for approval as specified in paragraph (3) are no longer met with respect to such product, or that other public health reasons, prescribed by regulation, exist. No action to revoke a license based on the findings of an inspection shall be initiated prior to the submission and review by the Secretary of a written response submitted by the licensee to a notice of inspection findings so long as such written response is received within 30 days after the date of receipt by the licensee of the findings. The revocation of any product license shall not prevent the continued use of any licensed biological product that has been sold and

delivered by the licensee unless the biological product is subject to recall under subsection (d).

''(B) If at any time before the Secretary has taken final action to revoke a license, the licensee requests an inspection by the Secretary to determine whether the licensee is in compliance with applicable standards, the Secretary shall conduct an inspection within 30 days after the date of the request. If the inspection confirms that the licensee is not in compliance with applicable standards, the 30-day requirement for inspection shall not apply to any subsequent request by the licensee under this subparagraph for inspection. If the inspection confirms that the licensee is in compliance with all applicable requirements, the Secretary shall withdraw any proposed action within 30 days after the inspection.

''(C) If the Secretary determines that conditions exist that constitute a danger to health, the Secretary shall suspend the license, notify the licensee that the licensee's license is suspended, and require notification of the suspension to any consignee. Within 30 days thereafter, the Secretary shall initiate the hearing process under subparagraph (A).

''(6) The requirements of paragraph (1) do not apply to a biological product for which there is in effect an inves-

tigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act.''.

(b) DELETION OF ELA REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(1) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(2) by redesignating paragraph (2)(A) as subsection (d)(1);

(3) by redesignating subparagraph (B) as paragraph (2); and

(4) in paragraph (2) (as so redesignated), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''.

(c) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package so as to falsify the label or mark.''.

(d) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows through

''other product aforesaid'' and inserting ''biological product''.

(e) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end thereof the following new subsections:

''(i)(1) For purposes of this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic biologic product (except for topically applied allergenic products used for the diagnosis of Type IV allergies), or arsphenamine or its derivative (or any other analogous biological product) applicable to the prevention, treatment, or cure of diseases or conditions of human beings.

''(2) The Secretary shall promulgate regulations under section 513(d) of the Federal Food, Drug, and Cosmetic Act to provide for the regulation of diagnostic testing kits using topically applied allergenic products as devices within the meaning of section 201(h) of such Act. Such regulations shall take into account the following—

''(A) topically applied allergenic products used for diagnostic testing elicit a biological response, not a chemical response, on the body;

''(B) diagnostic testing kits using topically applied allergenic products were commercially marketed prior to May 28, 1976;

''(C) diagnostic testing kits using topically applied allergenic products are appropriately classified as class II devices pursuant to section 513(a)(1)(B) of such Act, without need for a review by or recommendation from a classification panel under section 513(c) of such Act; and

''(D) clinical data are not required for purposes of determining substantial equivalence of diagnostic testing kits using topically applied allergenic products under section 513(i) of such Act.

''(3) Not later than 12 months after the date of the enactment of this Act, the Secretary shall issue proposed regulations under paragraph (2). Not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations under paragraph (2).

''(j)(1) Sections 505(i), 903, and 904 of the Federal Food, Drug, and Cosmetic Act shall apply to all biological products, and references in such sections to new drug applications shall be deemed to include product license applications for biological products.

''(2) Requirements involving labeling or advertising for biological products shall be established in accordance

with sections 201(m) and 502(n) of the Federal Food, Drug, and Cosmetic Act.''.

(f) STRENGTHENING REGULATION OF BLOOD AND BLOOD PRODUCTS.—The Secretary of Health and Human Services, in order to strengthen and streamline the regulation of blood and blood products, shall, after consultation with patient advocacy groups and the regulated industry, develop the concept of a single license for the regulation of blood and blood products that would, as appropriate, cover multiple individual locations that fall under a single management. The Secretary shall report the progress on achieving a single license to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by March 31, 1997.

SEC. 24. REQUIREMENTS FOR HUMAN TISSUE.

(a) IN GENERAL.—Section 201 is amended by adding at the end the following:

''(gg)(1) The term 'human tissue' means a collection of similar human cells which—

''(A) is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in man or for reproduction,

''(B) achieves its primary intended purpose through repair or replacement by structural support or cellular function and not systemic action,

''(C) may have been propagated or otherwise processed before use, and

''(D) may be combined with substances that are safe under conditions of intended use and not intended to provide a therapeutic effect.

''(2) The term human tissue does not include vascularized human organs, gene therapy, blood, blood components, milk, or human tissue combined with biomaterials.

''(3) Human tissue is not a drug, biological product, or device unless reclassified by the Secretary pursuant to 355 of the Public Health Service Act.

(b) REGULATION OF HUMAN TISSUE.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following section:

''REGULATION OF HUMAN TISSUE

''SEC. 352A. (a)(1) Human tissue shall be subject to regulation under this section only if the Secretary publishes a finding in the Federal Register, after a hearing before the Commissioner, that voluntary regulation under generally accepted scientific standards is inadequate to

protect the public health with respect to any particular type of human tissue or human tissue generally.

''(2) Human tissue shall not be subject to regulation as a drug, biological product, or device unless it is reclassified under subsection (e).

''(b)(1) Any person subject to regulation under this section who recovers, processes, stores, or distributes human tissue for transplantation or implantation in the United States shall register in accordance with the registration procedures established for drugs under section 510 of the Federal Food, Drug, and Cosmetic Act. Such registration shall contain the name of the person, the location of the facilities of the person, a list of the types of human tissue recovered, processed, stored, or distributed by the person, and a brief description of the basic method or methods of processing of such tissue.

''(2) A registered person shall be deemed to be authorized to conduct human tissue recovery, processing, storage, and distribution activities identified in its registration unless—

''(A)(i) the Secretary determines, upon inspection, that such person fails to meet applicable operating standards under subsection (c);

''(ii) the Secretary so notifies such person, advises the person of the steps necessary to meet such

standards, and provides the person with a reasonable opportunity to establish compliance with the standards;

''(iii) the Secretary determines, after an opportunity for an informal hearing, that the person has failed to establish such compliance within the applicable period and such failure constitutes a threat to the public health; and

''(iv) the Secretary suspends or revokes the authority to conduct such activities;

''(B) the Secretary determines, after an opportunity for an informal hearing, that such person has failed to comply with any patient registry or other retrospective patient data requirement, and the Secretary suspends or revokes the authority to conduct such activities; or

''(C) the Secretary determines that such person presents an immediate or substantial danger to the public health, and the Secretary suspends or revokes the authority to conduct such activities.

''(c) The Secretary may establish operating standards for human tissue that shall be limited to the following general requirements for the recovery, processing, storage, and shipment of human tissue:

''(1) Requirements for infection control designed to prevent transmission of disease.

''(2) Requirements for processing practices that assure the safety of, and prevent damage to, human tissue.

''(3) Requirements for labeling and record keeping to identify the type of tissue and any added foreign substance and to permit tracing.

''(d) A registered person may be required by the Secretary to maintain a patient registry or meet other retrospective patient data requirements if, after notice and an opportunity for comment, the Secretary finds that such tissue has been commercially available within the United States for a period of less than 5 years and that such data requirement is necessary to protect the public health.

''(e)(1) The Secretary may reclassify a particular type of human tissue as a drug, biological product or device if, after notice and an opportunity for comment, the Secretary finds that—

''(A) the particular type of human tissue is—

''(i) subject to a patient registry or other retrospective data requirement under which the collection of information has been required for at least 5 years (or such other time period as

agreed to by the Secretary and the registered person); and

''(ii) the information received from such patient registry or other retrospective data requirement is insufficient to confirm the safety and clinical benefit from the use of such tissue; or

''(B) a particular type of human tissue should be reclassified because it presents an imminent hazard to public health.

''(2) The Secretary may reclassify a human drug, biological product or medical device as human tissue if, after notice and an opportunity for comment, the Secretary finds that such previous classification is not necessary to protect public health.

''(3) The Secretary may reclassify a drug, biological product, device, or human tissue upon the petition of the sponsor of such drug, biological product, or device, or the registered person of such human tissue, if, after notice and an opportunity for comment, the Secretary finds that such reclassification is consistent with the protection of the public health.

''(f)(1) If the Secretary finds that a person violates any provision of this section or any regulations promulgated thereunder, and the Secretary finds the violation

constitutes a significant risk to the public health, the Secretary may issue an order that such person cease distribution of human tissue, or that human tissue recovered, processed, stored or distributed by such person be retained, recalled, or destroyed. After receipt of such an order, the person in possession of the human tissue shall not distribute or dispose of the human tissue in any manner inconsistent with the provisions of the order.

''(2) A person subject to an order under paragraph (1) may obtain an informal hearing regarding the order if the person requests such a hearing not later than 5 days after receiving the order. If the person makes such a request within such period, the Secretary shall conduct the hearing not later than 30 days after receiving the request and shall issue an order not later than 15 days after the hearing is conducted. Such order shall be considered a final order of the Secretary.

''(g) Each registered person shall be subject to inspection under section 704 of the Federal Food, Drug, and Cosmetic Act. The Secretary may, with the concurrence of the registered person, authorize an inspection to be conducted by a person specifically accredited by the Secretary to conduct such inspection under section 712 of such Act.

''(i) This section (including provisions regarding reclassification) shall apply with respect to cord blood to the same extent and in the same manner as this section applies with respect to human tissue.''.

(c) TRANSITION—The requirements of the interim regulation promulgated by the Secretary of Health and Human Services on December 11, 1993, shall remain in effect until amended or withdrawn by the Secretary. Any changes to such regulations after the date of the enactment of this Act are subject to this Act and the amendments made by this Act.

(d) EFFECTIVE DATE.—Section 352A of the Public Health Service Act shall take effect on June 30, 1997.

(e) CONFORMING AMENDMENTS.—

(1) ADULTERATION PROVISION.—Section 501 (21 U.S.C. 351) is amended—

(A) in the first sentence, by striking ''drug or device'' and inserting ''drug, device or human tissue''; and

(B) by inserting at the end thereof the following:

''(j) If it is human tissue and is recovered, processed, stored, or distributed by—

''(1) a registered person under section 352A of the Public Health Service Act whose failure to com-

ply with operating standards for human tissue consistent with such section constitutes a threat to the public health; or

''(2) a person who is required under such section to register but has failed to do so.''.

(2) MISBRANDING PROVISIONS.—Section 502 (21 U.S.C. 352) is amended—

(A) in the heading for the section, by striking ''MISBRANDED'' and all that follows and inserting the following: ''MISBRANDED DRUGS, DEVICES, AND HUMAN TISSUE''; and

(B) in the first sentence, by striking ''drug or device'' and inserting ''drug, device or human tissue''.

(3) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by inserting the following new section:

''(v) The adulteration or misbranding of any human tissue.''.

(4) SEIZURE.—

(A) Section 304 (a)(2)(D) (21 U.S.C. 334 (a)) is amended by inserting ''or human tissue'' after ''device.''

((B) Section 304(d)(1) is amended by deleting the ''or'' before ''cosmetic'' and inserting

‘‘, or human tissue’’ after ‘‘cosmetic’’ in the first sentence.

(5) INSPECTION.—Section 704(a)(1) (21 US.C. 374(a)(1)) is amended—

(A) in the first sentence, by inserting ‘‘human tissue,’’ after ‘‘device,’’ each place such term appears; and

(B) in the second sentence, by inserting ‘‘human tissue,’’ after ‘‘drugs,’’ each place such term appears.

SEC. 25. ACCESS TO UNAPPROVED THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end thereof the following:

‘‘SUBCHAPTER D—ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS

‘‘EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS

‘‘SEC. 543. (a) Any physician acting on behalf of a patient or a patient may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such a physician or patient after compliance with this section, an investigational drug for the diagnosis, monitoring, or treatment of a serious disease or condition, life-threatening or seriously debilitating disease or condition, and any other disease or condition designated by the

Secretary as appropriate for expanded access under this section by the physician or patient making the request if—

''(1) in the case of a physician acting on behalf of a patient the physician has no comparable or satisfactory alternative therapy available to treat, diagnose, or monitor the disease or condition; or

''(2) in the case of such a physician or patient, the risk to the physician or patient from the investigational drug or device is not greater than the risk from the disease or condition.

''(b) A manufacturer or distributor may submit to the Secretary one or more expanded access protocols covering expanded access use of a drug described in subsection (a). The protocols shall be subject to the provisions of section 505(i) for a drug and may include any form of use of the drug outside a clinical investigation, prior to approval of the drug for marketing, including protocols for treatment, use, emergency use, and uncontrolled trials and single patient protocols.

''(c) A manufacturer or distributor may charge for an investigational drug under an expanded access protocol, but the price of the drug or device may not be more than that necessary to recover the costs of manufacture, research, development, and handling for the drug or device.

''(d) The manufacturer or distributor may inform national, State, and local medical associations and societies, and voluntary health associations, about the availability of an investigational drug for expanded access use pursuant to this section but—

''(1) shall state that the drug is investigational;

''(2) shall not represent that the drug is safe or effective for any use; and

''(3) shall not otherwise promote or advertise the availability of the product for expanded access use.

SEC. 26. RADIOPHARMACEUTICALS.

Section 505(d) (21 U.S.C. 355(d)), as amended by section 5, is amended by adding at the end the following:

''(4)(A) For purposes of paragraph (1), the safety and effectiveness of a radiopharmaceutical intended to be used for purposes of diagnosis or monitoring shall be determined by—

''(i) weighing the probable benefit from the use of the radiopharmaceutical against any probable risk of injury or illness from such use; and

''(ii) taking into account the appropriate use of the radiopharmaceutical in the practice of medicine, the level of pharmacological and

toxicological activity of the radiopharmaceutical, and the estimated absorbed radiation dose of the radiopharmaceutical.

''(B) In the case of a radiopharmaceutical intended to be used for purposes of diagnosis or monitoring, the indications for which such a radiopharmaceutical is approved under this section may refer to manifestations of disease (such as biochemical, physiological, anatomical, or pathological processes) common to or present in one or more disease states or may refer to a diagnostic procedure used in the diagnosis of one or more diseases or conditions.

''(C) Within 180 days after the date of the enactment of this paragraph, the Secretary shall, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, issue guidelines pertaining to the evaluation, in accordance with this paragraph, of the safety and effectiveness of radiopharmaceuticals.

''(D) As used in this paragraph, the term 'radiopharmaceutical' means—

''(i) an article that is intended for use in vivo in the diagnosis, cure, mitigation, treat-

ment, or prevention of disease or a manifestation of disease in man, and that exerts its primary effect by the spontaneous disintegration of unstable nuclei with the emission of ionizing radiation; or

''(ii) a reagent kit or nuclide generator that is intended to be used in the preparation of any such article.''.

SEC. 27. PROTECTION OF CONFIDENTIAL INFORMATION.

Section 301, as amended by section 8(b), is amended by adding after paragraph (w) the following:

''(x) The release to the public of confidential patient and donor identifying information from establishments licensed or registered by the Secretary unless the release of such information is critical to a public health purpose.''.

SEC. 28. NATIONAL UNIFORMITY.

(a) Chapter VII is amended by adding at the end thereof the following:

''SUBCHAPTER D—NATIONAL UNIFORMITY

''SEC. 741. (a)(1) Except as provided in subsection (d)(1) or (e), no State or political subdivision of a State may establish or continue in effect any requirement—

''(A) that relates to the regulation of a drug or cosmetic, and

''(B) that is not identical with a requirement of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and the administrative implementation of such Acts.

''(2) Except as provided in subsection (d)(2) or (e), no State or political subdivision of a State may establish any requirement after the date of enactment of this section or continue in effect any requirement established after such date—

''(A) that relates to the regulation of food, and

''(B) that is not identical with a requirement of this Act or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) and the administrative implementation of such Acts.

''(b) For purposes of subsection (a)(1), a requirement that relates to the regulation of a drug or cosmetic shall be deemed to include any requirement that relates to the subject matter in any provision of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), including any notification requirement for a drug or cosmetic that provides for a warning concerning the safety of the drug or cosmetic or any component or package thereof, but shall not include any requirement that

relates to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

''(c) For purposes of subsections (b)—

''(1) the term 'warning' with respect to a drug or cosmetic means any statement, vignette, or other representation which indicates, directly or by implication, that the drug or cosmetic presents or may present a hazard to human health or safety; and

''(2) the term 'notification requirement' includes any mandatory disclosure requirement that relates to the dissemination of information about a drug or cosmetic in any manner, such as labels, labeling, posters, public notices, advertising, or any other means of communication.

''(d)(1) Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a)(1), under such conditions as the Secretary may impose, a State requirement which—

''(A) is justified by compelling and unique local conditions,

''(B) protects an important public interest that would otherwise be unprotected,

''(C) would not cause any drug or cosmetic to be in violation of any applicable requirement or prohibition under Federal law, and

''(D) would not unduly burden interstate commerce.

''(2)(A) A State may establish a warning notification requirement for food that would otherwise violate subsection (a)(2) if—

''(i) the warning is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences or death, and

''(ii) a petition for an exemption is submitted by the State no later than 7 days after the warning notification requirement is established and is not subsequently denied by the Secretary.

The Secretary shall take action on a petition no later than 30 days after its submittal.

''(B) For purposes of subparagraph (A)—

''(i) the term 'warning' with respect to a food means any statement, vignette, or other representation which indicates, directly or by implication, that the food presents or may present a hazard to human health; and

''(ii) the term 'notification requirement' includes any mandatory disclosure requirement that

relates to the dissemination of information about a food in any manner, such as labels, labeling, posters, public notices, advertising, or any other means of communication.

''(e) An application described in paragraph (1) or a petition described in paragraph (2) of subsection (d) that demonstrates that a drug, cosmetic, or food during the period of its likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent application or petition. If an order by the Secretary to grant or deny the requested authorization in an urgent application or petition is not made within 30 days of receipt of the application or petition, the State may establish and enforce a temporary requirement. The temporary requirement shall be validated or terminated by the Secretary's final order on the application or petition.

''(f) Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.''.

SEC. 29. CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS.

Chapter IX is amended by adding at the end the following section:

"SEC. 909. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner, shall establish a demonstration program for the purpose of making 1 or more grants for the establishment and operation of 1 or more centers to carry out the activities specified in subsection (b).

''(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

''(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

''(A) To increase awareness of new uses of drugs, devices, or biological products and the unforeseen risks of new uses of drugs, devices, or biological products.

''(B) To provide objective clinical information to the following entities:

''(i) Health care practitioners or other providers of health care goods or services.

''(ii) Pharmacy benefit managers.

''(iii) Health maintenance organizations or other managed health care organizations.

''(iv) Health care insurers or governmental agencies; and

''(C) To improve the quality of health care while reducing the cost of health care through the prevention of adverse effects of drugs, devices, or biological products and the consequences of such effects, such as unnecessary hospitalizations.

''(2) The conduct of research on the comparative effectiveness and safety of drugs, devices, or biological products.

''(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

''(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1997 and $3,000,000 for fiscal year 1998.''.

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